DEC 2 1 2010

510(k) SUMMARY

Submitter's Name	Gambro Renal Products, Inc.
Address	14143 Denver West Parkway, Suite 400 Lakewood, Colorado 80401
Establishment Registration Number	2087532
Contact Person	Kae Miller, Regulatory Affairs Manager
Telephone Number	303.222.6724
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Date Summary Was Prepared	December 02, 2010

Device Information	
Name of the Device	GamCath® High Flow Dolphin® Catheter
Common or Usual Name	Short-Term Hemodialysis Catheter
Classification Name	Catheter Hemodialysis Non-Implanted
Device Class	II
Product Code	MPB
Regulation Number	21 CFR 876.5540

Predicate Device Information (1)	
Name of the Device	GamCath® High Flow Catheter
510(k) Number	K040301
Classification Name	Catheter Hemodialysis Non-Implanted
Device Class	II
Product Code	MPB
Regulation Number	21 CFR 876.5540

Predicate Device Information (2)	
Name of the Device	Medcomp Duo-Flow II Catheter with Lubricious Heparin
510(k) Number	K991320
Classification Name	Catheter Hemodialysis Non-Implanted
Device Class	II
Product Code	MPB
Regulation Number	21 CFR 876.5540

DEVICE DESCRIPTION

The GamCath® High Flow Dolphin® Catheters are single use medical devices for short term use to obtain vascular access in patients with acute or chronic renal failure. The GamCath® High Flow Dolphin® Catheter combines the GamCath® High Flow Catheter with an additional coating based on a block copolymer. The polymer layer results in a surface structure that locks in barium sulfate particles. The coated catheter is free of heparin, therefore the use of the catheter is not contraindicated in patients with HIT syndrome.

Catheters made of Polyurethane are equipped with small rotatable Polypropylene suture rings, still allowing rotation of catheter when sutured to skin. Polyurethane Extension lines, present on each lumen, are equipped with PVC luer-lock connectors according to ISO 594-1 with Polyethylene protection caps and are provided with clamps which may be color coded to indicate the venous (blue), arterial (red). Clamp inserts bear easily legible and permanently fixed imprints indicating usable catheter length and outer diameter of catheter shaft (in French calibration) as well as priming volumes. The Catheter is available in 13 French and 11,5 French straight and curved extension line configuration. An inner dilator made of FEP is provided in the venous lumen for insertion. The insertion length is available in range from 150 mm (5.906") up to 250 mm (9.843"). The Dolphin coating is a co-polymer film which is applied over the catheter surface to form a continuous surface that has a smoother surface morphology than an untreated catheter. The copolymer film is formed by providing a hydrophobic polymer block, such as polydimethylsiloxan (PDMS) with functional –OH end groups.

INDICATIONS FOR USE

GamCath® High Flow Dolphin® catheters are indicated for use in attaining short term vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian or femoral vein. GamCath® High Flow Dolphin® Catheter is not intended for use in pediatric patients.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

The GamCath® High Flow Dolphin® Catheter is substantially equivalent to the GamCath® High Flow Catheter, K040301 and the MedComp Duo-Flow II Catheter with Lubricious Heparin manufactured by Medical Components, Inc. K991320.

Substantial equivalency was shown by detailed comparisons of Intended Use, Patient Population, Mode of Operation, Labeling and Catheter Type. Technological characteristics showed substantial equivalency with respect to material of the catheter (Connector, Catheters Tube, Extension Line), position of insertion of the catheter, sizes of the catheter, design/physical characteristics (number of lumens, sterility, distal end configuration, intended anatomical location of distal end, proximal end configuration).

Both GamCath® High Flow Dolphin® Catheter and MedComp Duo-Flow II Catheter are having a coating. The materials used differ. MedComp Duo-Flow II Catheter uses a lubricious heparin coating whereas GamCath® High Flow Dolphin® Catheter uses the Dolphin® coating. The Dolphin coating is a co-polymer film which is applied over the catheter surface to form a continuous surface. In general the copolymer film is formed by providing a hydrophobic polymer block, such as polydimethylsiloxan (PDMS) with functional –OH end groups. The reliance of Dolphin coating was placed on testing against recognized standards to evaluate safety and performance (see section non-clinical performance data below). GamCath® High Flow Dolphin® catheter coating is free of heparin; therefore the use of the catheter is not contraindicated in patients with HIT syndrome.

NON-CLINICAL PERFORMANCE DATA

The non-clinical tests submitted included biocompatibility data as per ISO 10993-1 (including Cytotoxicity, Sensitization, Intracutaneous reactivity, Acute Systemic toxicity, Genotoxicity, and Hemolysis). Ethylene Oxide sterilization was validated as per ISO 11135-1 and 10993-7. Package integrity testing was done successfully.

Substantial equivalence versus the predicate device was shown by the following tests: Integrity of the catheter was shown by testing for air leakage and liquid leakage as per ISO 10555-1. Clamping tests up to 300 cycles were done to prove absence of visible delamination or visible detachable particles. Pressure in the catheter was measured over the range of flow rates. Performance data was collected to verify tensile strength according ISO 10555-1 of Connector to extension line, Extension line to hub (bifurcation), Hub to catheter shaft, and Catheter shaft to tip.

CONCLUSION OF SAFETY AND EFFECTIVENESS

The comparison of technological characteristics demonstrated that GamCath® High Flow Dolphin® Catheters are substantially equivalent to the predicate devices. The GamCath® High Flow Dolphin® Catheters met all performance criteria of the test performed and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Kae Miller
Regulatory Affairs Manager
Gambro Renal Products, Inc.
14143 Denver West Pkwy, Suite 400
LAKEWOOD CO 80401

DEC 2 1 2010

Re: K100451
Trade/Device Name: GamCath® High Flow Dolphin® Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB
Dated: December 6, 2010
Received: December 7, 2010

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GAMBRO Renal Products

Traditional 510(k) for GamCath® High Flow Dolphin® Catheter

Indications for Use Statement

510(k) Number (if known): K100451

Device Name: GamCath® High Flow Dolphin® Catheter

DEC 2 1 2010

Indications for Use Statement:

GamCath® High Flow Dolphin® catheters are indicated for use in attaining short term vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian or femoral vein. GamCath® High Flow Dolphin® Catheter is not intended for use in pediatric patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100451